

SEP 25 2002

K.020199

**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:**

**Locking Reconstruction Plate with Attachable Condylar Head**

**General Information**

Proprietary Name:	Locking Reconstruction Plate with Attachable Condylar Head
Common Name:	Bone Plate with Mandibular Condyle Prosthesis
Proposed Regulatory Class:	Class III
Device Classification:	MPL 872.3960, Mandibular Condyle Prosthesis
Submitter:	Stryker Leibinger 4100 East Milham Avenue Kalamazoo, MI 49001 616-323-7700 x3295
Submitter's Registration #:	1811755
Manufacturer's Registration #:	8010177
Contact Person:	Robin L. Rowe Regulatory Affairs Representative Telephone: 616-323-7700 x3295 Fax: 616-324-5412
Summary Preparation Date:	January 17, 2002

## **Intended Use**

The Locking Reconstruction Plate with attachable Temporary Condylar Head is intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

## **Device Description**

The temporary Condylar Plate is manufactured as a single piece (plate with prosthesis) subsequently fixated to the mandible via locking and/or normal fixation screws. The temporary Condylar Prosthesis is an independent prosthesis rigidly connected to a standard or locking reconstruction plate via connecting screws, which has had previous 510(k) clearance under K854886. The connecting screws are manufactured from a Titanium Alloy (ASTM F136-98)

## **Substantial Equivalence**

The Locking Reconstruction Plate with Attachable Temporary Condylar Head is substantially equivalent to the Synthes Locking Reconstruction Plate with Condylar Head, K990637, Wurzburg Titanium Mini-Bone-Plates & Screw K854886, and Leibinger BoneLock Endosseous Implant K954030.



Robin L. Royce  
Regulatory Affairs Representative  
January 17, 2002



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Stryker Instruments  
Ms. Robin Rowe  
Stryker Leibinger  
4100 East Milham Avenue  
Kalamazoo, Michigan 49001

SEP 25 2002

Re: K020199

Trade/Device Name: Locking Reconstruction Plate with Attachable Condylar Head  
Regulation Number: 872.3960  
Regulation Name: Mandibular Condyle Prosthesis  
Regulatory Class: III  
Product Code: MPL  
Dated: August 26, 2002  
Received: August 30, 2002

Dear Mr. Rowe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

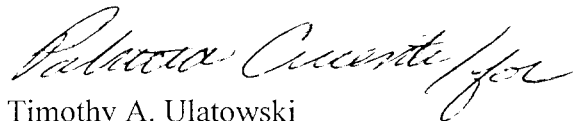
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Timothy A. Ulatowski".

Timothy A. Ulatowski

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): \_\_\_\_\_

Device Name: Locking Reconstruction Plate with Attachable Condylar Head

Indications For Use:

The Locking Reconstruction Plate with attachable Temporary Condylar Head is intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The- Counter Use

(Optional Format 1-2-96)

Susan Perez

(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K020199